

REMARKS

These remarks are in response to the Official Action mailed August 19, 2003, in which claims 1-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Errico et al., U.S. Patent No. 5,575,792 ("Errico") in view of Barker et al., U.S. Patent No. 6,280,442 ("Barker").

Claim 1 has been amended so as to overcome a 35 U.S.C. § 112 rejection for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the phrase "in particular" has been cancelled from the claims, as highlighted by the Examiner in the Official Action. Additionally, claims 4-11 have also been amended to be in proper dependent form, specifically claims 4-11 are no longer multiple-dependent claims which depend from another multiple-dependent claim.

Applicants have also added claims 12-35 to the present application. No new matter has been added by any of these amendments.

With regard to the obviousness rejection, Applicants wish to point out that Barker is not prior art as against the present application. The present application has a priority date of July 22, 1999, corresponding with the filing of the French Priority Application. Barker, which the Examiner cites as being prior art to the present application, has an earliest priority date of September 1, 1999 as disclosed on the front page of the patent. Thus, Barker is not prior art to the present application and cannot be combined with another patent so as to render obvious the claims of the present application.

Applicant has also amended claim 1 to more clearly define the present invention. Amended claim 1 now includes the

recitation that the housing is deformed inward when the connecting member is loaded against a portion of the connector.

Independent claim 12 has been added to the application and includes the recitation that the seat of the second housing includes at least two raised ends. Similarly, independent claims 25 and 35, include recitations directed towards the first housing having slots and a means for clamping the rod against the seat of the second portion, respectively. No new matter has been added by these amendments and additions.

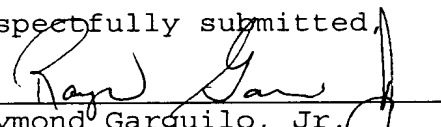
As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that the Examiner telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which the Examiner might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: December 18, 2003

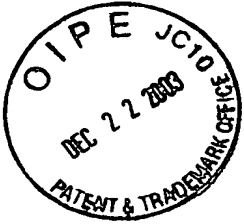
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Application No. : 10/031,563

Docket No. : SPINE 3.3-400



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## MULTIAXIAL CONNECTION FOR OSTEOSYNTHESIS

### BACKGROUND OF THE INVENTION

[0001] The present invention relates to a multiaxial connection osteosynthesis system, in particular for the spine.

[0002] In the context of surgery ~~on~~ to the vertebral column, ~~for example,~~ and in particular when using a posterior approach route, the surgeon is often confronted with the problems of misalignment of the anchor members and interference between anchor members on two adjacent vertebrae. This problem increases the operating time or prevents the surgeon from carrying out the desired procedure under the best possible conditions. The cause of this problem is that the coupling member located between the member connecting the various vertebrae ~~together~~ and the anchor member implanted in the vertebra is rigidly connected to the anchor member.

[0003] Reference Document WO 97/02786 discloses a multiaxial connection between the members. The anchor member has a hemispherical head. The coupling member includes, in addition to means for receiving the member connecting the various vertebrae together, a split chamber in its bottom part adapted to receive the hemispherical head. The external surface of the coupling member includes a cone that is flared toward the bottom end. A clamping collar can be threaded over the top portion of the coupling member to bear on the conical portion. Before tightening, the coupling member is free to rotate relative to the anchor member. Locking in position is effected when tightening the member connecting the vertebrae together. which ~~The member~~ bears on the clamping collar, while ~~which~~ at the same time closes the receiving chamber on

the hemispherical head of the anchor member.

[0004] The complexity of the positional locking mechanism, because of its large number of components, obliges the surgeon to carry out supplementary manipulations, and consequently increases the operating time.

[0005] An object of the present invention is to provide a multiaxial connecting device that is simple to use and requires only a small number of operations to complete assembly~~fit it~~.

#### SUMMARY OF THE INVENTION

[0006] To achieve this object, the present invention provides a multiaxial connection osteosynthesis system, in particular for the spine, including a bone anchor member having a head, a connecting member, a connector having a first ~~deformable~~ housing with a recess adapted to receive the head and a second housing adapted to receive the connecting member<sub>7</sub>. The system further includes including clamping means, i.e. a locking member such as, for example, an axially moveable screw, for clamping the connecting member in the second housing. The connector is arranged so that<sub>7</sub> when the clamping means load the connecting member in the second housing, the connecting member loads ridges of the connectors directly to reduce the dimension of the recess of ~~deform~~ the first housing and immobilize the head therein.

[0007] Thus the first deformable housing is closed onto the head. This reduces the number of components and therefore simplifies the use of the device.

[0008] The first housing may advantageously include a chamber with a concave surface. The concave surface chamber is advantageously complementary to all or part of the convex surface of the head. The first housing advantageously includes a cavity adapted to receive part of the head.

[0009] The connector ~~advantageously~~ includes a slot in the

first housing. Thus the first housing can have a more pronounced elastic deformability while inserting the head and while locking ~~of~~ the device into position.

[0010] The head may advantageously include ~~has a~~ spherical part.

[0011] The first housing advantageously includes ~~has a~~ U-shaped opening having an axis and two branches at a distance from and facing each other. The slot is located advantageously preferably perpendicular to the axis of the U-shaped opening. The branches of the U-shaped opening may include advantageously have a screwthread. The clamping means may advantageously include a locking member adapted to engage between the branches of the U-shaped opening. The clamping means or locking element may additionally advantageously include a flange adapted to fit around the branches of the U-shaped opening. Accordingly, when clamping the nut, the flange prevents spreading of the branches of the U-shaped opening. The screwthread may have ~~advantageously has a~~ face substantially perpendicular to the axis of the thread and oriented in a penetration direction of the clamping means on the connector.

[0012] Accordingly, during clamping, the face substantially perpendicular to the axis of the thread of the locking member comes into contact with the face of the branches of the U-shaped opening. The reaction force generated in this way is substantially parallel to the axis of the thread and this minimizes the radial reaction force. the radial reaction force would spread apart the branches of the U-shaped opening. ~~which would otherwise~~

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Other features and advantages of the present invention will become more apparent in the course of the following description of three preferred embodiments, which

description is given by way of non-limiting examples. In the accompanying drawings:

[0014] Figure 1 shows is a partial perspective side view of a first embodiment of the present invention~~system~~;

[0015] Figure 2 shows is an exploded perspective view of the system shown in Figure 1;

[0016] Figure 3 shows is a cross-sectional view of the system shown in Figure 1 in section taken along the line III-III in figure 1;

[0017] Figure 4 is a top perspective view of the a-first embodiment of the present invention~~connector~~;

[0018] Figure 5 is a bottom perspective view of the connector shown in Figure 4;

[0019] Figure 6 is a cross-sectional view of the connector shown in in section taken along the line VI-VI in Figure 4;

[0020] Figure 6a is a diagrammatic sectional view of the Christmas tree thread of the connector shown in Figure 4;

[0021] Figure 7 is a bottom perspective view of a second embodiment of the present invention~~connector~~; and

[0022] Figure 8 is a bottom perspective view of a third embodiment of the present invention~~connector~~.

#### DETAILED DESCRIPTION

[0023] A first embodiment of the present invention is described with reference to Figures 1 to 6a.

[0024] The osteosynthesis system includes at least two vertebral anchor members 2, connecting means 4, such as a rod, extending between the anchor members 2 and the other anchor members (not shown) of the osteosynthesis system, a connector 6 adapted to be fitted to the member 2, and a clamping means, i.e. a locking member 8 adapted to cooperate with the connector 6.

[0025] The vertebral anchor member 2, which here in the preferred embodiment takes the form of a bone screw, may have

~~has~~ a circular section cylindrical threaded body 10 carrying a bone thread (not shown). The preferred member 2 also may have ~~has~~ a head 12 with a convex surface 14. The convex surface 14 has a ~~here a~~ surface of revolution whose axis coincides with the axis of the screw ~~16~~. The convex surface has a spherical lateral portion 18, a flat top portion 22, perpendicular to the axis of the screw, and a connecting fillet 20 between them, as shown in Figure 3. The head 12 includes cavity means 24 for operating the screw 2, here in the form of a hexagonal socket 24.

[0026] As shown in Figure 2, ~~Here~~ the locking member 8 may be ~~is~~ generally screw-shaped and have ~~has~~ a thread 26 adapted to cooperate with the thread 28 on the connector 6, described hereinafter. The latter also includes socket operating means 30 in the form of a hexagonal socket 30.

[0027] The connector 6 provides a coupling member between the bone screw 2 and the connecting rod 4. The general shape of the coupling member is that of a circular section cylinder. As shown in Figure 6, ~~it~~ has a top portion 6a, for connecting ~~it~~ to the rod 4 and a bottom portion 6b for connecting ~~it~~ to the bone screw 2.

[0028] As shown in Figures 4 and 5, ~~T~~the top portion 6a of the coupling member 6 includes a U-shaped opening 32 which has an axis 42 and is delimited by two facing branches 34 at a distance from each other. The two branches 34 constitute two sectors of a common circular section cylinder forming the coupling member 6. The cylindrical external faces 36 of the branches 34 are coaxial and smooth. They can include grooves ~~holding means~~ 38, for example, in the form of a notch on each of the branches 34. The grooves 38 have ~~with~~ a flat bottom parallel to the axis 42 of the U-shaped opening 32. The grooves ~~notches~~ 38 are symmetrical mirror images of each other with respect to the median plane of the U-shaped opening 32.

The cylindrical inside faces 28 of the branches are coaxial and threaded. Their thread is adapted to cooperate with that of the locking member 26.

[0029] The two threads 26 and 28 are complementary and are referred to as "Christmas tree" threads. As shown in Figure 6, ~~The~~ thread 28 has a first face 80 substantially perpendicular to the axis of the thread. ~~A,~~ a second face 81 substantially parallel to the axis of the thread delimits ~~ing~~ the bottom of the thread. ~~A,~~ a third face 83 opposite the first face 80 and ~~which~~ can be inclined in the direction of the axis relative to the direction of the first face 80. Lastly, ~~and~~ a fourth face 82 located substantially parallel to the axis of the thread, delimits ~~ing~~ the crest of the thread. The thread 26 is substantially complementary to the thread 28. The thread 26 has a first face 90 parallel to and complementary to the face 80, a second face 91 substantially parallel to the axis of the thread delimiting the crest of the thread, a third face 93 substantially parallel to and complementary to the face 83, and a fourth face 92 substantially parallel to the axis of the thread delimiting the bottom of the thread. During clamping, the face 90 of the thread 28 comes into contact with the face 80 of the thread 26. The reaction force  $F_r$  generated in this way has a normal component  $F_n$  parallel to the axis of the threads and a transverse component  $F_s$  in the radial direction. The transverse component  $F_s$  may ~~could~~ cause the branches 34 to spread during tightening of the locking member 8, but the particular shape of the threads 26, 28 previously referred to reduces the transverse component  $F_s$  and therefore reduces the spreading of the branches 34 during clamping.

[0030] In a plane perpendicular to the axis 42, the bottom 40 of the U-shaped opening is semicircular to receive the connecting rod 4, with a diameter equivalent to that of the



connecting rod 4. On the other hand, the bottom 40 has a concavity in the median plane of the U-shaped opening 32 with a center of curvature situated on the same side as the portion 6a of the connector 6. Finally, the bottom 40 has ends 44 parallel to the axis 42, providing a seat to receive the connecting rod 4.

[0031] The bottom portion 6b of the connector 6 includes a housing 46 opening onto the bottom face 48 at an insertion orifice 50 and opening onto the bottom 40 of the U-shaped opening 32 at a communication orifice 52. The circular section insertion orifice 50 allows the head 12 of the bone screw 2 to be inserted into the housing 46. The housing 46 has a part-spherical bottom chamber 54 adapted to receive the head 12 of the bone screw 2. The shape of the bottom chamber 54 is complementary to the spherical lateral portion 18 of the convex surface 14 of the head 12. A slot 56 crosses the bottom part 6b diametrically. The slot 56 is perpendicular to the axis 42 of the U-shaped opening 32. It extends downward as far as the bottom face 48 of the connector 6 and upward until it opens onto the bottom 40 of the U-shaped opening 32. Thus the bottom part 6b is divided into two subparts 58 and 60 which are symmetrical mirror images of each other with respect to the median plane of the slot 56. The slot 56 facilitates clipping the head 12 into the coupling member 6 by facilitating deformation of the receiving space 46.

[0032] Prior to the procedure, each connector 6 is premounted by clipping it onto the head 12 of the bone screw 2. The bone screw is implanted in the patient using an instrument inserted into the cavity ~~operating means~~ 24 via the communication orifice 52. When the screw 2 has been implanted, the connector 6 is free to rotate relative to the screw 2. The connector and the screw are connected together by a ball-and-socket connection formed by the head 12 and the

bottom chamber 54. The rod 4 is fitted into the U-shaped opening 32 so that it rests on the ends 44 of the bottom 40. The locking member 8 is then engaged between the branches 34 of the opening 32 with the threads 26 and 28 interengaged with each other. The locking member 8 is then pressed against the rod 4 and the surgeon tightens the locking member 8. The locking member 8 bears on the rod 4. The rod 4 bears on the ends 44 of the bottom 40, which is then deformed because of the presence of the slot 56 perpendicular to the axis 42 of the opening 32, which is closed up as the two subparts 58 and 60 move toward each other. Consequently, the receiving space 46 and the chamber 54 are closed up onto the head 12 of the bone screw 2, locking the assembly in position, rigidly immobilizing the connector on the head of the bone screw.

[0033] In the second embodiment, shown in figure 7, the modifications relative to the first embodiment relate to the bottom part of the connector 106. The housing 146 no longer includes a spherical chamber, but instead is in the shape of a circular cylinder with two flats 102 and 104. The radius of the circular portion 108 can be equivalent to the radius of the head 12 of the bone screw 2. The two flats 102 and 104 are parallel to the slot 56. A circular section hole 110 perpendicular to the flats 102 and 104 passes completely and diametrically through the bottom part in the area of the flats and perpendicularly thereto. The diameter of the hole 110 is substantially equivalent to the width of the flats 102 and 104.

[0034] When the connector 106 is clipped to the head 12 of the bone screw 2, the head 12 locates in the holes 110, leaving free the ball-and-socket connection formed in this way.

[0035] The use of this embodiment is identical to that of the first embodiment during clamping, the deformation of the

receiving space 146 by the movement toward each other of the two subparts 158 and 160 obliging the two flats 102 and 104 to move toward each other, thereby immobilizing the head 12 of the bone screw 2 in the holes 110.

[0036] In the third embodiment, shown in figure 8, the modifications relative to the previous embodiment relate to the bottom part of the connector 206. The housing 246 and the slot 256 are coincident, the slot 256 being the same width as the housing 246. The width L of the slot 256 is less than the diameter of the head 12 of the bone screw 2. As in the preceding embodiment, a circular section hole 210 passes completely through the bottom part of the connector 206 in the area of the flats and perpendicularly thereto, diametrically and perpendicularly to the walls of the slot 256. The diameter of the hole 210 is less than that of the spherical part 18 of the convex surface 14 of the head 12.

[0037] The clipping is effected in the same manner: the head 12 is accommodated in the holes 210, leaving free the ball-and-socket connection formed in this way.

[0038] The use of this embodiment is identical to that of the second embodiment. The locking in position is similar.

[0039] Of course, many modifications can be made to the invention without departing from the scope of the invention.

[0040] The anchor members can be hooks. The clamping means can include a ring or a flange adapted to be threaded over the branches of the U-shaped opening instead of or in addition to the locking member. In the latter case, the flange or ring can be connected to the locking member.

[0041] The thread cooperating with that of the branches can be on the flank, the branches being threaded on their outside face.

[0042] Although the invention herein has been described with reference to particular embodiments, it is to be

understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

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